DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Division of Clinical Laboratory Improvement & Quality (DCLIQ)
Western and Central Operations Branch - San Francisco Office
(Denver, Kansas City, San Francisco, and Seattle)
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: DCLIQ - GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

Via facsimile to (661) 402-6485.
(Confirmation of successful facsimile transmission constitutes proof of receipt.)

February 28, 2022

Adam Rosendorff, M.D., Director
CDPH Branch Laboratory
28454 Livingston Avenue
Valencia, CA 91355

CLIA Number: 05D2197416

RE: PROPOSED SANCTIONS NOT IMPOSED

ALLEGATION OF COMPLIANCE CREDIBLE, EVIDENCE OF COMPLIANCE ACCEPTABLE

CONDITIONS MET, IMMEDIATE JEOPARDY REMOVED

Dear Dr. Rosendorff:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Laboratories are required to be in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

By letter dated May 6, 2021, we notified you that based on an onsite CLIA initial certification and complaint survey completed on May 6, 2021, your facility was not in compliance with Condition-level CLIA requirements and that conditions within the laboratory pose immediate jeopardy (*see* 42 C.F.R. § 493.2). In our letter, we requested that your laboratory submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies.

In response, we received a submission from the laboratory on May 16, 2021. After careful review, we determined that the laboratory's submission did not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA initial certification and complaint survey completed on May 6, 2021. The submission did not demonstrate that the laboratory had come into Condition-level compliance and abated immediate jeopardy.

Consequently, by letter dated July 6, 2021, C.M.S. notified the laboratory of proposed sanctions against the laboratory's CLIA certificate based on the findings of immediate jeopardy, the laboratory's failure to meet all CLIA Condition-level requirements, and based on the failure by the owners and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited during the CLIA initial and complaint survey completed on May 6, 2021. This letter described the proposed sanctions and gave the laboratory ten days from the date of the July 6, 2021 letter to submit, in writing, any information or evidence as to why these sanctions should not be imposed.

Your laboratory responded with a two-part second submission, which we received on July 16, 2021, and August 11, 2021. We carefully reviewed the second submission and determined that the response had no effect on our determination to impose sanctions. That is, this submission did not constitute a credible allegation of compliance and acceptable evidence of correction. The information provided showed that the laboratory continued to be out of compliance with the CLIA requirements as cited during the May 6, 2021 survey and that the determination of immediate jeopardy continued to exist.

However, before we imposed the proposed sanctions, C.M.S. representatives conducted an onsite visit to determine whether our determination of the laboratory's submissions was correct by providing the laboratory with an opportunity to discuss the submissions. This onsite visit was completed on August 24, 2021. Subsequent to our August 24, 2021, onsite visit, we received an unsolicited third submission from the laboratory on September 10, 2021. After careful review, we determined that, collectively, the three submissions constituted a credible allegation of compliance and acceptable evidence of correction and that the determination of immediate jeopardy had been removed.

As advised in our May 6, 2021 letter, to verify that corrections to the deficiencies cited had been effectuated, C.M.S. representatives conducted an onsite follow-up survey that was completed on February 14, 2022. As a result of the onsite follow-up survey, we are not imposing the sanctions proposed in our July 6, 2021 letter, and we are recommending the laboratory for certification in the CLIA Program. Shortly, the laboratory will receive a CLIA certificate bill. The laboratory will receive its CLIA Certificate of Compliance approximately two weeks after payment is posted.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following

all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

Please contact Gary Yamamoto by telephone at (415) 744-3738 or by e-mail at gary.yamamoto@cms.hhs.gov with any questions concerning this letter.

Sincerely,

Karen Fuller/s

Karen Fuller, Manager
Division of Clinical Laboratory
Improvement & Quality (DCLIQ)
Western and Central Operations Branch
(Denver, Kansas City, San Francisco, and
Seattle)

cc: California Department of Public Health, Laboratory Field Services